

AUG - 1 1996

510(k) Summary - Cath Caddie, submitted by Mark-Clark, a division of M-C Industries, Inc.

The Cath Caddie was developed by the grandmother of a pediatric cancer patient who received chemotherapy via a Hickman Catheter placed in his chest. Constant removal of taped dressings resulted in skin irritations to the youth.

The inventor created the Cath Caddie for her grandchild to eliminate the need for tape. Subsequently, she provided Cath Caddies for several additional patients of Dr. David Rosen. She estimates that Dr. Rosen has issued as many as 1,500 of the covers through his practice and through the Children's Miracle Network. (See attached photo-copy of letter from Dr. David Rosen.)

Additional prototypes of the Cath Caddie were provided to Dr. Jerry H. Feagan who in turn passed them on to the Endoscopy and Surgery Center of Topeka. This practice utilized the Cath Caddie to cover and secure PEG tubes of enteral feeding tubes in the abdomens of some of their patients. Elizabeth Thomas, administrator of the center found the Cath Caddie to be superior and much more convenient than the use of taped dressings for this purpose.

This product - both in theory and in actual practice - appears to provide an actual benefit to patient and doctor alike. The elimination of tape prevents typical skin irritation caused by adhesives. Obviously, this provides improved patient comfort while also avoiding the risk of infection possible with skin sores. This helps to avoid additional healthcare costs associated with treating secondary problems (skin sores) and eliminates ongoing expense of tape and gauze dressings to the physician's practice.